

MAR 22 2006

K 060411

510(k) SUMMARY

Radiancy (Israel) Ltd. Radiancy ClearTouch Lite™ Acne Clearance System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Manufacturer: Radiancy (Israel) Ltd.
9 Gan Rave Street
Industrial Park
Yavne
Israel
Telephone: +972-8-9438010
Facsimile: +972-8-9438020

Contact Person: Margaret Fourte
Director, Clinical and Regulatory Affairs
Radiancy, Inc.
40 Ramland Road
Orangeburg, NY 10972
Telephone: (845) 398-1647
Facsimile: (845) 398-1648
Email: margaret@radiancy.com

Date Prepared: February 15, 2006

Name of Device and Name/Address of Sponsor

Trade/Proprietary Name: Radiancy ClearTouch Lite™ Acne Clearance System
Common Name: Pulsed Light System and Light Unit Assembly
Classification Name: Laser surgical instrument for use in general and plastic surgery
and in dermatology (21 C.F.R. § 878.4810)

Manufacturing Facility: Radiancy (Israel) Ltd.
9 Gan Rave Street
Industrial Park
Yavne, Israel

Establishment
Registration Number: 9616256
Owner/operator number: 9040071

Predicate Devices

Radiancy Acne System with ClearTouch™ Light Unit Assembly (K032205, K051268)

Device Description

The ClearTouch Lite™ is a pulsed-light, manually controlled system designed to deliver light in a sequence of pulses to treat mild and moderate inflammatory acne.

Intended Use / Indications for Use

The ClearTouch Lite is intended to provide phototherapeutic light to the body. The ClearTouch Lite is generally indicated to treat dermatological conditions. The ClearTouch Lite is specifically indicated to treat mild and moderate inflammatory acne, which includes pustular inflammatory acne in patients with Fitzpatrick skin types I-VI.

Technological Characteristics

The ClearTouch Lite that is the subject of this 510(k) notice is similar to the predicate device already cleared to provide phototherapeutic light to the body, except that the ClearTouch Lite xenon lamp emits lower energy intensity pulses compared to the predicate device delivery of similar energy in a single pulse.

Substantial Equivalence

The Radiancy ClearTouch Lite Acne Clearance System has the same intended use and the same indications for use, principles of operation and similar technical characteristics as the Radiancy Acne System with ClearTouch Light Unit Assembly predicate, which has already been cleared by FDA. The cleared Radiancy Acne System predicate and the ClearTouch Lite are generally indicated to treat dermatological conditions. The ClearTouch Lite and the Radiancy Acne System are specifically indicated to treat mild and moderate inflammatory acne, which includes pustular inflammatory acne in patients with Fitzpatrick skin types I-VI. The minor difference between the Radiancy ClearTouch Lite delivery of a fixed sequence of lower intensity pulses and the predicate delivery of a single pulse does not raise any new issues of safety and effectiveness. Thus, the Radiancy ClearTouch Lite is substantially equivalent to the predicate.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 22 2006

Radiancy, Ltd.
c/o Radiancy, Inc.
Ms. Margaret Fourte
Director, Clinical and Regulatory Affairs
40 Ramland Road South – Suite 10
Orangeburg, New York 10962

Re: K060411

Trade/Device Name: Radiancy Clear Touch Life™ Acne Clearance System

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and
in dermatology

Regulatory Class: II

Product Code: GEX

Dated: February 15, 2006

Received: February 16, 2006

Dear Ms. Fourte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Form

510(k) Number (if known): K 060411

Device Name: Radiancy ClearTouch Lite™ Acne Clearance System

Indications for Use:

The Radiancy ClearTouch Lite Acne Clearance System (ClearTouch Lite) is intended to provide phototherapeutic light to the body. The ClearTouch Lite is generally indicated to treat dermatological conditions. The ClearTouch Lite is specifically indicated to treat mild and moderate inflammatory acne, which includes pustular inflammatory acne in patients with Fitzpatrick skin types I-VI.

Prescription Use X

OR

Over-The-Counter Use _____

(Per 21 C.F.R. 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K060411